K080126

Attachment 4.

APR 11 2008

510(k) Summary

DIO Protem Implant System

1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, Korea Phone: 82-55-383-7900 Fax : 82-55-363-3404
2. US Agent / Contact Person	Hyungick Kim 3540 Wilshire Blvd. #1104 Los Angeles, CA 90010, USA Phone : 213-365-2875, Fax : 213-365-1595
3. Date Prepared	January 08, 2008
4. Device Name	DIO PROTEM IMPLANT SYSTEM (2.0/2.5MM)
5. Classification Name	Endosseous Dental Implant System
6. Device Classification	Class II Dental Devices panel Regulation Number: 21 CFR 872.3640
7. Predicate Devices	DIO Protem Implant System(510(k) No: K06710568)
8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.
9. Purpose	The purpose of this 510(k) is to change the some information of prior 510(k) submission for the DIO Protem Impalnt System.

10. Device Description

DIO Protem Implant System consists of Protem Implants, Superstructure, Prosthetics and Surgical Instruments.

The Protem Implants is an integrated system of endosseous dental implants which designed to protect main implant from immediate loading during osteointegration period, to increase indurance of temporary tooth and to conduct the immediate functions and immediate recovery of aesthetics of osteoimplanted area. These are made of titanium alloy which have a sand-blasted, RBM(Resorbable Blast Media) treated surface. These implants are consist of one-stage, root-form dental implants which provide the clinician to maintain the patients' gingival contour. The Implants have the diameter(2.0/2.5mm) and length.(8/10/12/14mm).

The superstructures consist of Protem Cemented Abutment, Ball Cap and Healing Cap.
The Protem Cemented Abutments are made of titanium and intended for cement-retained restorations where conventional crown & bridge techniques are required. It can be used for single or multiple unit restorations. Ball Cap intended to retain the O-ring inside of the denture. Healing Cap is fixed on the ball type fixture to protect the direct pressure reduce the motion of fixture.

The Prosthetics and Surgical Instruments provide the clinician to choose only those components required for each clinical situation.

The implants are gamma sterilized and intended to single use. And the surgical tools are non-gamma sterilized and have to be sterilized by user before using.

11. Packing / Labeling / Product Information

DIO Protem Implant System(2.0/2.5mm) follows the guidance of the 21 CFR 872.3640.

12. Intended Use

The DIO Protem Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

13. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Device Name	DIO Department, DSI, Inc. (DIO Protem Implant System(2.0/2.5mm))	DIO Department, DSI, Inc. (DIO Protem Implant System) **K070568**
Intended Use	Identical to predicate devices	The DIO Protem Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.
Material	Titanium alloy	Titanium alloy
Screw Threads	YES	YES
Implant Thread Diameter (mm)	2.0 and 2.5	2.0 and 2.5
Lengths(mm)	8-14 mm	8-14 mm
Surface Treatment	Sanded	Sanded
Sterilized	YES	YES

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

DIO Department, DSI, Incorporated
C/O Mr. Hyungick Kim
Manager
DIO, USA
3540 Wilshire Boulevard, Suite 1104
Los Angeles, California 90010

Re: K080126
Trade/Device Name: DIO Protem Implant System (2.0/2.5mm)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 27, 2008
Received: April 3, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

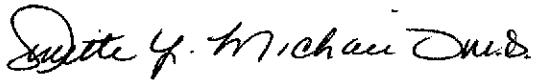
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2.

Indication for Use

510(K) Number (if known): K080126

Device Name: DIO Protem Implant System.(2.0/2.5mm)

Indications For Use:

The DIO Protem Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080126

Prescription Use X AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _1_